

progression. Unfortunately, in parallel with decreasing funding opportunities, publishing in respected journals has grown more difficult. Thus, early career academic cardiologists might greatly benefit from dedicated space in a high-impact journal such as *Journal of the American College of Cardiology (JACC)*.

There are important factors that need to be considered carefully before launching an exclusively early career journal. We should avoid the appearance of an early career journal as a reservoir of less than compelling research. Additionally, starting a journal is a large undertaking that requires commitment of resources from the American College of Cardiology and our academic workgroup. In an environment of limited means, a more effective use of resources is to dedicate funding and mentorship to early career cardiologists and trainees. With this support, early career investigators will have greater chances of publishing in well-respected pre-existing journals.

There are alternatives to launching a new journal that still provide publication space for early career members. For example, in *JACC* or one of its associated journals, there could be a dedicated issue each year or one paper per issue that highlights research of emerging young investigators. Other paper types include reviews or viewpoint pieces that particularly address issues, challenges, and opportunities for early stage investigators. Furthermore, we could ask early career members to rotate on the editorial board to ensure the review process has an early career perspective; this would also provide a valuable career development opportunity for these junior investigators.

We appreciate the passion and the novel proposal of Drs. Shenoy and Tuliani. It has stimulated our workgroup to consider these important issues, which we plan to discuss further with forthcoming recommendations to promote greater development and flourishing of early stage investigators.

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Ejection Fraction May Improve But the Scar Still Exists! The Risk May Be Lower But Not Zero



We read with great interest the report by Kini et al. (1). The results are interesting, and the authors make a strong case against the clinical utility and cost-effectiveness of continued generator replacements in patients with implantable cardioverter-defibrillators who have improved ejection fraction (EF). We disagree with the conclusions of the authors and find it rather bold to arrive at such sweeping recommendations based on limited data. In this study, 8% (n = 5) of the 59 patients received appropriate therapy despite improvement in EF over a mean of 3.5 years, for an event rate of 2.8% per person-year or 1.4% per year (n = 5/3.5 years). This rate is much higher than the 0.1% risk of sudden cardiac death in the general population (2). If the general population is considered a control group, then the absolute risk reduction is 1.3% with a number needed to treat of 76. With that number needed to treat, we find it hard to explain the recommendation that a potentially lifesaving therapy should be withheld. Again, if we consider all patients who had an improvement in EF to >35%, we would include the 8 patients who had an event before generator replacement despite an EF >35%, which would increase the event rate to 20% (n = 13 of 67) or 3.7% per year. This reduces the number needed to treat even further. Although EF, which is the surrogate marker for the risk of sudden cardiac death, may improve over time, the scar that is the substrate for reentry is unlikely to resolve, especially in patients with ischemic cardiomyopathy (3). The cost-effective analysis used in the current paper is not robust either. Thus, until larger studies are reported that can effectively predict those who are at risk for sudden cardiac death despite improvement in EF, we should continue to replace generators after a thorough discussion with the individual patient respecting his or her preferences.

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**REPLY: Ejection Fraction May Improve
But the Scar Still Exists! The Risk
May Be Lower But Not Zero**



We thank Dr. Pillarisetti and colleagues for their interest in our report (1). However, we disagree with the conclusions they have drawn from additional analysis of our data. They argue that patients with primary prevention implantable cardioverter-defibrillators (ICDs) who experience no appropriate ICD therapy and demonstrate improvement of left ventricular ejection fraction (LVEF) to $\geq 40\%$ should routinely undergo generator replacement (GR). To further this argument, they have analyzed the event rate (appropriate ICD therapy) of 2.8% per person-year that we observed in the group of patients who underwent GR despite improved LVEF and have derived a number needed to treat (NNT) of 76 to prevent 1 appropriate ICD therapy. They further contend that the NNT may have been lower if patients who experienced appropriate ICD therapy despite improvement in LVEF before GR were included. However, their latter contention is invalid because in our study these patients fulfilled secondary prevention indications for ICD therapy. This point notwithstanding, is an NNT of 76 to prevent 1 appropriate ICD therapy sufficient to justify routine GR?

In the largest trial assessing efficacy of primary prevention ICD therapy, i.e., SCD-HeFT (Sudden Cardiac Death in Heart Failure Trial) (2), the NNT with ICD to prevent 1 death was 20. Similar NNTs have been shown for other lifesaving advances in cardiology that have gained widespread acceptance. For example, the NNT with primary coronary angioplasty (versus thrombolytic therapy) to prevent 1 death from acute myocardial infarction is 10 (3), and the NNT with beta-blockers in chronic heart failure to prevent 1 death is 15 (4). While it is unclear (and subjective) what an “acceptable” NNT should be for GR in recipients of primary prevention ICD, an NNT of 76 to prevent 1 appropriate device therapy (which is not synonymous with mortality) is clearly much higher

than what has been shown with other lifesaving cardiovascular therapies. Furthermore, the potential risks of the GR procedure must be taken into account. Data from the REPLACE (Implantable Cardiac Pulse Generator Replacement) registry show that the major complication rate for patients undergoing ICD GR is 5% (5). This would imply that for 1 patient to receive appropriate ICD therapy after GR, 4 patients would experience a major complication from the procedure.

The principle of nonmaleficence necessitates weighing any lifesaving benefit against the potential for harm. The latter in patients undergoing ICD GR includes inappropriate shocks, pocket or device infections, device malfunction, and manufacturer recalls. Why an approach of LVEF reassessment and informed discussion regarding the uncertain benefits and risks of GR in this patient population, as suggested by our study, is perceived as “bold and sweeping” by Dr. Pillarisetti and colleagues remains unclear to us. In any situation in which there is significant uncertainty regarding the benefits of a treatment, deferring to patient preference after sharing all the relevant information without bias is, in our opinion, the optimal approach.

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